DEPARTMENT OF HEALTH & HUMAN SERVICES

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Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

March 17, 2000

WARNING LETTER

Michael J. Collins, President
Pharmaceutical Specialties Division
Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

KAN #2000-010

Dear Mr. Collins:

During an inspection of your drug manufacturing facility located at 3600 North 2nd Street, St. Louis, Missouri, conducted on January 18 to February 16, 2000, our investigators found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals regulations (21 CFR, Part 211). These deviations relate to the production of inorganic salts, which are used as drug excipients. Excipients are drug components as defined by Section 201(g)(1)(D) of the Federal Food, Drug, and Cosmetic Act (Act). These deviations cause these inorganic salts to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Our investigation found a failure to perform complete compendial testing on individual batches of inorganic salts prior to their release. It was observed that multiple batch samples are composited as a single lot sample, which is then given full compendial testing. The batches that comprise a lot are not further blended but remain separate batch entities when released. This process could allow for problems with individual batches to go undetected.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of drug products, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. At the conclusion of the inspection a Form FDA 483, Inspectional Observations, was issued to and discussed with Ms. Rita Blesser, Vice President and General Manager. This form is a comprehensive listing of the investigators' observations of deviations found during the inspection. You should take prompt action to correct these violations and to establish procedures to prevent their recurrence.

We acknowledge that a response dated February 23, 2000, was submitted to this office by Ms. Rita Blesser, concerning our investigators' observations noted on the Form FDA 483. Ms. Blesser's letter was reviewed and taken into account for the preparation of this letter.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may address your reply to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Mary Woleske

Mary H. Woleske
Acting District Director
Kansas City District

cc: Rita E. Bleser, Vice President
and General Manager
Mallinckrodt, Inc.
3600 North 2nd Street
P.O. Box 5439
St. Louis, MO 63147-0339